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# 510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI Omega21™ System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

**Contact Person:** Frederic Testa
Telephone: (973) 299-9300

Date prepared: December 14, 2001

2. **Proprietary Name:** EBI Omega 21™ System
**Common Name:** Spinal Fixation Device
**Classification Names:** Spondylolisthesis Spinal Fixation Device System
Spinal Intervertebral Body Fixation Orthosis
Spinal Interlaminal Fixation Orthosis

3. **Predicate or legally marketed devices that are substantially equivalent:**

- EBI Omega 21™ System (K001357, K992333, K991721, K990303, and K973683)

4. **Description of the device:** The EBI Omega 21™ System is a spinal fixation device that uses rods, screws, couplers, and hooks. This submission is for the addition of top loading hooks to supplement the existing system.

5. **Intended Use:** The EBI Omega 21™ System is a spinal fixation device for pedicle screw fixation and a nonpedicle hook and sacral/iliac screw fixation system of the noncervical spine.

When used as a pedicle screw fixation system, in the non-cervical spine of skeletally mature patients, the System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocations, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system in skeletally mature patients, it is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior hook and sacral/iliac screw fixation system, the levels of attachment are the lumbar and thoracic spine, and screw fixation limited to the sacrum and ilium. The System is intended for the treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudarthrosis, stenosis, scoliosis, spondylolisthesis, fracture, previous failed fusion, or tumor resection.

When used as an anterior fixation system, the levels of attachment are the anterolateral vertebral bodies of the lumbar and thoracic spine. The System is intended for the treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudarthrosis, stenosis, scoliosis, spondylolisthesis, fracture, previous failed fusion, or tumor resection.

6. **Materials:** The components of the system are manufactured from Ti-6Al-4V ELI per ASTM F136.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI Omega 21™ System and other currently marketed spinal systems. It is substantially equivalent* to the predicate devices in regards to intended use, materials and function. Testing comparing the modifications to the previous system demonstrated that the device complies with applicable standards and meets all of its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frederic Testa
Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

JAN 1 6 2002

Re: K014137
Trade Name: EBI Omega 21™ System
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3070, 21 CFR 888.3050, 21 CFR 888.3060
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation, Orthosis, Spondylolisthesis Spinal Fixation Device System, Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP, KWQ
Dated: December 14, 2001
Received: December 17, 2001

Dear Mr. Testa:

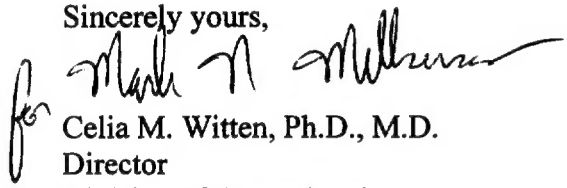
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## STATEMENT OF INDICATIONS FOR USE



510(k) Number (if known): K014137

Device Name: EBI Omega 21™ System

for Mark N Milleman
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014137

Indications For Use:

The EBI Omega 21™ System is a spinal fixation device for pedicle screw fixation and ~~a non-pedicle hook~~ and sacral/Iliac screw fixation system of the non-cervical spine.

When used as a pedicle screw fixation system, in the non-cervical spine of skeletally mature patients, the System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of nuerologic impairment, fracture, dislocations, scoliosis, kyphosis, spinal tumor, and failed previous fusion. (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system in skeletally mature patients, it is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5 – S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior hook and sacral/Iliac screw fixation system, the levels of attachment are the lumbar and thoracic spine, and screw fixation limited to the sacrum and ilium. The system is intended for the treatment of degenerative disk disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, stenosis, scoliosis, spondylolisthesis, fracture, previous failed fusion, or tumor resection.

When used as an anterior fixation system, the levels of attachment are the anterolateral vertebral bodies of the lumbar and thoracic spine. The system is intended for the treatment of degenerative disk disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, stenosis, scoliosis, spondylolisthesis, fracture, previous failed fusion, or tumor resection.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)